

Appl. No. : 10/517,908
Filed : January 30, 2006

REMARKS

By way of summary, Claims 1-29 were pending in this application prior to this response. In the outstanding Office Action, Claims 1, 2, 7-9, 15 and 24-25 were rejected under 35 U.S.C. §102(b) as being anticipated by Yarger (U.S. 5,360,414). Claims 3-5, 11-12, 16, 19, 22 and 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Breznock (U.S. 6,638,253). Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Cambron (U.S. 6,017,493). Claims 13, 14, 17, 18, 20, 21, 28 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Wakabayashi (U.S. 6,352,525). In this Amendment, Claims 1, 4, 12, 13, 15, 16, 19, 20, 22 and 26 have been amended. Claims 30 and 31 have been added and correspond to original claims 6 and 23, respectively, which were previously canceled. Accordingly, Claims 1-5, 7-22, and 24-31 are currently pending.

1. Claim Amendments

In this Amendment, Claims 1, 4, 12, 13, 15, 16, 19, 20, 22 and 26 have been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. However, to expedite prosecution, Applicant has amended the claims in order to clarify the features of Applicant's claimed invention. Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date.

2. Claims 1, 2, 7-9, 15 and 24-25 are not anticipated, and cannot be rendered obvious by Yarger

In the outstanding Office Action, Claims 1, 2, 7-9, 15 and 24-25 were rejected under 35 U.S.C. §102(b) as being anticipated by Yarger (U.S. 5,360,414). Applicant respectfully disagrees with this rejection because Yarger does not disclose, teach, or suggest all the limitations of the referenced claims.

Yarger discloses a suction tube with holes connected to several channels along the length of the surface of the tube, where the proximal end of the tube is designed to be connected to a

suction source. Yarger Abstract. Yarger describes the suction source as a vacuum source for sump action, which is known in the art to be a **low, or weak vacuum**, and states that:

“Typically, the vacuum source is a combination suction and drainage collection device. One example of such devices is a **squeeze bulb**, not shown, which is collapsed by squeezing to create a suction in the tube assembly 40. As the squeeze bulb is filled, it expands until no further suction is present. At that point, the squeeze bulb may be conveniently emptied. The type of suction/collection device is not intended to constitute the present invention per se.”

Yarger col. 7, ll. 40-48. Certain figures from the Yarger reference are reproduced for the convenience of the Examiner:

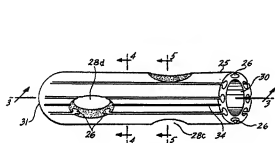


Fig. 2

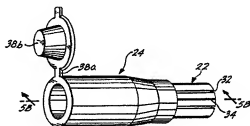


Fig. 5A

Applicant respectfully submits that Yarger does not disclose, teach, or suggest the limitations recited at least in independent Claims 1, 15 and 20.

Claim 1 recites, among other things, a “first end adapted to connect to a vacuum source of at least approximately 125 torr.” Applicant respectfully disagrees with Examiner’s characterization of Yarger disclosing any vacuum source or system approximating 50 torr. Office Action p. 2. As stated above, Yarger only contemplates a suction device such as a squeeze bulb, which is understood in the art to exert only a small suction pressure. Without reciting more, one skilled in the art could only conclude from Yarger that the disclosed device uses a very low vacuum pressure. As stated in the Applicant’s specification, “[e]xisting chest drainage systems conventionally use a low vacuum pressure. In such systems, the vacuum pressure applied to the chest tube is normally -20 cmH₂O (= 14.7 torr) or less. A dry unit with a pressure gauge may use higher pressure, but only slightly higher.” Applicant specification at [0007]. The Applicant’s specification goes on to state, “[e]xisting chest drainage systems use a

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conventional vacuum pressure of 14.7 torr. Presently, vacuum pressure in and around the range of 25-35 torr is considered to be ‘high suction pressure.’” Applicant specification at [0022].

Claim 15 recites, among other things, a “high vacuum pressure body cavity drainage system, comprising ... a vacuum source of approximately 125 torr or greater.” As discussed above, Yarger discloses no device for working with a vacuum source of approximately 50 torr or greater, much less a vacuum source of approximately 125 torr or greater. Furthermore, Claim 15 recites, among other things, that “the suction force conveyed at any of the side holes is less than capillary pressure in the animal.” None of the references, including Yarger, compares or compares pressure at any of the holes with capillary pressure in any animal. None of the cited references discloses, teaches, or contemplates the use of “a vacuum source of approximately 125 torr or greater” with “the suction force conveyed at any of the side holes is less than capillary pressure in the animal” as claimed, in part, in Claim 15.

Claim 20 recites, among other things, “a vacuum source of approximately 125 torr or greater,” a “vacuum end of said connector adapted to receive a vacuum force” and “a vacuum chamber, said vacuum chamber having a gas outlet port coupled to said vacuum source, said vacuum chamber having an inlet port coupled to said vacuum end of said connector, said inlet port communicating a vacuum force from said gas outlet port to said vacuum end of said connector, said vacuum chamber having a fluid drainage outlet port through which fluid matter from said body cavity flows in a direction away from said body cavity.” As discussed above, Yarger discloses no device for working with a vacuum source of approximately 125 torr or greater and does not disclose any vacuum chamber, much less any vacuum chamber claimed in Claim 20.

Thus, Applicant respectfully submits that Yarger fails to teach or suggest all the limitations of Claim 1, 15 or 20. Accordingly, Applicant respectfully requests that the rejection of Claims 1 and under § 102 based on Yarger be withdrawn.

Claims 2, 7-9 and 24-25 depend from independent Claims 1, 15 and 20 and are allowable for the same reasons set forth above with respect to Claims 1, 15 and 20 in addition to the patentable subject matter contained therein. Accordingly, Applicant respectfully requests that the rejection of Claims 1, 2, 7-9, 15 and 24-25 under § 102(b) based on Yarger be withdrawn.

Furthermore, with respect to Claims 8-9 and 24-25 Applicant respectfully disagrees with the Examiner characterization that Yarger discloses a hole that has an area no greater than that of a circle having a diameter of 1 mm, or a hole that has an area no greater than that of a circle having a diameter of 0.5 mm at Col. 5, lines 2-7. Office Action p. 2-3. At Col. 5, lines 2-7 Yarger states: "In this regard, preferably the width of the entrance channels 32 may range from 0.1 mm to 1.0 mm, depending on the type of tissue and debris desired to be excluded, the overall diameter of the tube section, and also the volume of the wound to be drained."



Fig. 4.

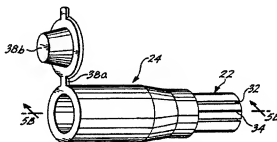


Fig. 5A.

As can be seen in Figs. 4 and 5 at reference numeral 32, Yarger is discussing the **width of a channel that runs the length of the tube, not a hole diameter**. The area defined by Yarger would far exceed the area claimed because the 0.1 mm to 1.0 mm width dimension would need to be multiplied by the entire length of the tube to correspond to the area of the channels. Accordingly, Applicant respectfully requests that the rejection of Claims 8-9 and 23-25 under § 102(b) based on Yarger be withdrawn.

3. All Claim Rejections Fail to Provide Proper *Graham* Factual Inquiries and Fail to Articulate Findings under the KSR Examination Guidelines

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* ("Examination Guidelines"), which were published in the Federal Register Vol. 72, No. 195 (Docket PTO-P-2007-0031) on October 10, 2007, clarify the Supreme Court's decision on *KSR Int'l. v. Teleflex, Inc.* with regard to the issue of obviousness under 35 U.S.C. §103(a) in relation to prior art. *KSR Int'l. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 2007). Applicant submits that the outstanding Office Action fails to satisfy the Examiner's burden in establishing an obviousness rejection.

Under the Examination Guidelines, and as reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in *Graham v. John Deere Co.* Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art.

The Examination Guidelines confirms the role of Patent Office personnel as fact finders:

When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

72 Fed. Reg. 57527 (Oct. 10, 2007).

The Examination Guidelines further provide that “Once the *Graham* factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.” *Id.* “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* at 57528-57529 (internal citations omitted). Under the Examination Guidelines, a rejection must offer specific support for the following rationales Examiners may use to show obviousness:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or

- other market forces if the variations would have been predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Id. at 57529.

For example, in order to reject a claim on rationale (G) above, Office personnel must first resolve the *Graham* factual inquiries, and then must articulate the following:

- (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- (2) a finding that there was reasonable expectation of success; and
- (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

Id. at 57534. The rationale to support a conclusion that the claim would have been obvious is that “a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.” *Id.* If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. *Id.* An explicit suggestion to combine the prior art is not necessary, but “[i]n such situations, the proper question is whether the ordinary artisan possess knowledge and skills rendering him capable of combining the prior art references.” *Id.* (internal citations omitted).

The present November 9, 2007 Final Office Action fails to set forth the level of ordinary skill in the pertinent art, or who qualifies as one of ordinary skill in the field. Applicant submits that without such a finding, the Examiner’s combinations are improper, as the Examiner has not established that the references proposed by the combinations would be known to one of ordinary skill in the art, nor that one of ordinary skill would have the requisite knowledge and ability to make the desired combinations. Moreover, the Examiner has failed articulate specific rationales for the proposed combinations of references, and has failed to provide explicit explanations supporting the obviousness rejections. Rather, the Examiner makes merely conclusory statements regarding the combinability of the cited prior art references, without identifying the

knowledge one skilled in the art would possess, what modifications the skilled person would need to make to combine the prior art references, and whether that skilled person would have a reasonable expectation of success. Accordingly, Applicant submits that the Examiner's obviousness rejections are improper. More specific details relating to these missing inquiries and missing articulated findings are discussed in more detail below, along with Applicant's reasoned statements explaining why Applicant's claims are nonobvious over the cited art.

4. Claims 3-5, 11-12, 16, 19, 22 and 26-27 cannot be rendered obvious by Yarger in view of Breznock

In the outstanding Office Action, Claims 3-5, 11-12, 16, 19, 22 and 26-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Breznock (U.S. 6,638,253). Claims 11, 12, 16 and 27 have been canceled. As discussed above, Yarger does not anticipate the claims of the present application. Dependent claims 3-5, 11-12, 16, 19, 22 and 26-27 depend from independent Claims 1, 15 and 20. For at least the reasons set forth above with respect to Claims 1, 15 and 20 Applicant respectfully submit that Claims 3-5, 11-12, 16, 19, and 22 are patentable over Yarger in view of Breznock. Claims 3-5, 11-12, 16, 19, and 22 are also are patentable over Yarger in view of Breznock in view of the additional limitations recited in each of the claims.

Further, Applicant respectfully disagrees with this rejection because the combination of Yarger and Breznock do not disclose, teach, or suggest all the limitations of the referenced claims.

Applicant respectfully disagrees with the Examiner characterization that Breznock discloses a vacuum source of approximately 100 torr or greater (citing Col. 4, lines 32-52 for Claim 3 and Col. 8, lines 28-37 for claims 19 and 22). Office Action p. 4. Within Col. 4, lines 32-52 Breznock states:

“At least a portion of the tubing 22 is preferably stiffened with a helical winding of material such as stainless steel, nitinol and the like. The stiffening 30 could also be created using corrugations in the tubing 22 or by addition of a strong polymer such as glass-filled polycarbonate instead of the metal helical winding. The stiffening member 30 serves the purpose of preventing collapse of the cannula 10 when vacuum is applied to the drainage lumen 32.”

The Examiner's cited paragraph does not disclose any particular vacuum levels, and instead illustrates aspects of Breznock teaching away from the Applicant's Claim 3. Breznock relies on the use of additional structure of helical winding materials to prevent collapse of the tube under even normal vacuum conditions, and does not present a solution for high vacuum tubes that do not use helical supports as is claimed in Claim 3. Regarding Claims 19 and 22, within Col. 8, lines 28-37 Breznock states: "The typical vacuum system is operated by an electrical vacuum pump and regulator to maintain a low level vacuum of 1 to 100 mm Hg. **Preferably, the vacuum is maintained at a level of 1 to 20 mm Hg.**" Notably, "a vacuum source ... of approximately 100 torr or greater" is not within Breznock's preferred range up to 20 mm Hg. Notably, the Applicant's pending claims relate to a vacuum source of at least approximately 125 torr, which is not disclosed, taught or suggested by the cited references.

With respect to Claim 5, Applicant respectfully disagrees with the Examiner characterization that Breznock discloses at least 100 holes relying on Fig. 1 and Col. 4, lines 64-67 and Col. 5, lines 1-5. Office Action p. 4. Fig. 1 from Breznock, reproduced below, does not show at least 100 holes in the wall, it shows about 18 holes.

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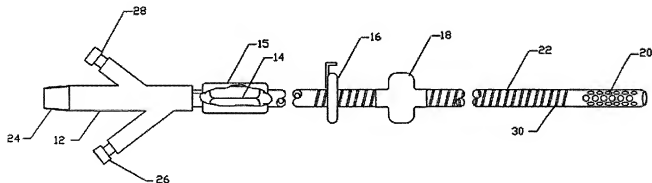


Figure 1

The present Office Action asserts that "Breznock discloses 'holes 20 are of sufficient size and quantity' which puts no limit on the total number of holes." Office Action p. 8. However, the complete statement at Breznock Col. 4, lines 64-67 and Col. 5, lines 1-5 states in relevant part, "The holes 20 are of sufficient size and quantity **to allow for passage of fluid, thrombus and**

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debris that might need to be removed from the chest cavity.” This does not disclose over 100 holes. It merely states in general terms that there should be big enough holes and numerous enough holes to take debris from a chest cavity.

Claim 26 recites, among other things, a “means for receiving a vacuum source of approximately 125 torr or greater.” As discussed above, Yarger, Breznock and any combination of Yarger and Breznock fail to disclose a device for working with a vacuum source of approximately 125 torr or greater. Dependent claim 27 depends from independent Claim 26. For at least the reasons set forth 26 Applicant respectfully submit that Claim 27 is patentable over Yarger in view of Breznock. Claim 27 is also are patentable over Yarger in view of Breznock in view of the additional limitations recited in each of the claims.

Further, with regard to independent Claim 26, Applicant respectfully disagrees with Examiner’s characterization that Col. 8, lines 28-37 in Breznock discloses “a means for regulating a respective suction force applied at each of a multiplicity of locations such that each of a respective suction forces is incapable of injuring bodily tissue exposed within a body cavity.” Office Action p. 4. Breznock Col. 8, lines 28-37 discloses stopping a vacuum system to cause a valve 14 to close and seal a drainage lumen 32. Applicant asserts that this disclosure does not apply to a means for regulating a respective suction force applied at each of a multiplicity of locations such that each of a respective suction forces is incapable of injuring bodily tissue exposed within a body cavity.

Accordingly, for all the reasons discussed above, Applicant respectfully requests that the rejection of Claims 3-5, 11-12, 16, 19, 22 and 26-27 as being unpatentable over Yarger in view of Breznock be withdrawn.

5. Claim 10 cannot be rendered obvious by Yarger in view of Cambron

In the outstanding Office Action, Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Cambron (U.S. 6,017,493). As discussed above, Yarger does not anticipate the claims of the present application. Further, Applicant respectfully disagrees with this rejection because the combination of Yarger and Cambron do not disclose, teach, or suggest all the limitations of the referenced claims. Applicant asserts that one skilled in the art would not have found a reason to combine Yarger with Cambron, and that the Examiner has not explicitly articulated any reason why one skilled in the art would have combined the prior

art elements in the manner claimed by the Applicant. Furthermore, the combination frustrates the intended purpose of the primary reference, rendering the device of the primary reference inoperable for its intended purpose.

As discussed above, the Examination Guidelines discuss the Examiner's burden in establishing an obviousness rejection in light of the Supreme Court's decision on *KSR Int'l. v. Teleflex, Inc.* In making a rejection under 35 U.S.C. §103(a) based upon a combination of prior art elements, Applicant submits that the Examiner must expressly identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. Beyond the conclusory statements made in the Office Action, the Examiner has failed to do so.

Furthermore, one skilled in the art would not look to Cambron to modify the tube of Yarger, because in order to make the primary Yarger method and device operable the Yarger device uses a plurality of holes in the wall of the tube to remove debris. In contrast, Cambron discloses tables and statistics on catheter diameters for tubes vacuum assisted venous drainage reservoirs with only a single orifice at the distal tip of the Cambron tube. From the disclosure, and even in the tables cited by the Examiner, a pressure measurement is taken at the distal orifice. The cited tables, reproduced below indicate a pressure measurement only at a reservoir end and a cannula end:

TABLE III

(Cannula Size = 20 Fr)

Pressure Measurements				
Hand Height (inch)	Vacuum (mmHg)	Pump Flow (lpm)	@ Cannula End (mmHg)	@ Reservoir End (mmHg)
6	0	.83	-32	6
6	-15	1.19	-46	-11
6	-30	1.50	-59	-26
6	-45	1.75	-73	-45
6	-60	2.06	-86	-61
6	-75	2.30	-99	-77
12	0	1.20	-47	-1
12	-15	1.48	-57	-14
12	-30	1.79	-71	-30
12	-45	2.03	-84	-46
12	-60	2.31	-98	-63
12	-75	2.53	-111	-78
18	0	1.75	-41	7
18	-15	2.18	-55	-6
18	-30	2.56	-70	-19
18	-45	2.82	-82	-32
18	-60	3.15	-95	-44
18	-75	3.52	-109	-57

TABLE IV

(Cannula Size = 18 Fr)

Pressure Measurements				
Hand Height (inch)	Vacuum (mmHg)	Pump Flow (lpm)	@ Cannula End (mmHg)	@ Reservoir End (mmHg)
6	0	.67	-34	3
6	-15	1.81	-104	-80
12	0	.89	-45	3
12	-15	1.13	-57	-11
12	-30	1.43	-72	-29
12	-45	1.67	-86	-45
12	-60	1.94	-102	-65
12	-75	2.12	-115	-80
18	0	1.00	-55	3
18	-15	1.22	-70	-16
18	-30	1.62	-84	-34
18	-45	1.79	-96	-47
18	-60	2.00	-112	-67
18	-75	2.17	-127	-86

Information that might be useful in vacuum tube applications with a single distal orifice does not apply to the structurally distinct characteristics of a vacuum tube with a plurality of holes along its walls.

Further, the combination frustrates the intended purpose of the primary reference, rendering the device of the primary reference inoperable for its intended purpose. A single orifice would not dissipate the suction on surrounding tissue through the set of parallel channels as disclosed in Yarger, putting the patient at serious risk of internal tissue damage.

Therefore, even if the Examiner could expressly identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed, the combination frustrates the intended purpose of the primary reference, rendering the device of the primary reference inoperable for its intended purpose. Furthermore, even if the references were combined, Yarger and Cambron fail to produce the claimed embodiment of Applicant's invention because Yarger and Cambron, alone or in combination, fail to disclose a device as claimed in Claim 10. Accordingly, for all the reasons discussed above, Applicant respectfully requests that the rejection of Claim 10 as being unpatentable over Yarger in view of Cambron be withdrawn.

6. Claims 13, 14, 17, 18, 20, 21, 28 and 29 cannot be rendered obvious by Yarger in view of Wakabayashi

In the outstanding Office Action, Claims 13, 14, 17, 18, 20, 21, 28 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Yarger in view of Wakabayashi (U.S. 6,352,525). As discussed above, Yarger does not anticipate the claims of the present application. Independent Claim 20 has been discussed with respect to Yarger above. Claims 13, 14, 17, 18 and 21 depend from independent Claims 1, 15 and 20. Applicant respectfully submits that Claims 13, 14, 17, 18 and 21 are patentable over Yarger in view of Wakabayashi. Claims 13, 14, 17, 18 and 21 are also are patentable over Yarger in view of Wakabayashi in view of the additional limitations recited in each of the claims. Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 13, 14, 17, 18 and 21 based on Yarger in view of Wakabayashi.

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7. New Claims

The new claims 30 and 31 are the same as the originally filed Claims 6 and 23, which were canceled in the previous office action. In the previous office action response, the language of canceled claim 6 was placed in independent Claim 1, and the language of canceled claim 23 was placed in independent Claim 20. In this response, Claims 1 and 20 were amended to remove the added language, which was placed back in dependent claim form in new claims 30 and 31, respectively. Each depend from Independent Claims 1 and 20, respectively, which are discussed above. Applicant respectfully submits that Claims 30 and 31 are patentable in light of the cited references for the reasons stated above with respect to Claims 1 and 20. Claims 30 and 31 are also are patentable in view of the additional limitations recited in each of the claims.

8. Conclusion

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or prior art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, he is invited to telephone

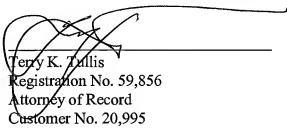
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Applicant's attorney of record so that extended prosecution of this application may be avoided. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 01-08-08

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